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McCullough, A. R., Ryan, C., Macindoe, C., Yip, N., Bradley, J. M., O'Neill, B., Elborn, J. S., & Hughes, C. M. (2016). Behavior change theory, content and delivery of interventions to enhance adherence in chronic respiratory disease: A systematic review. *Respiratory Medicine*, 116, 78-84. <https://doi.org/10.1016/j.rmed.2016.05.021>

[Link to publication record in Ulster University Research Portal](#)

Published in:
Respiratory Medicine

Publication Status:
Published (in print/issue): 01/07/2016

DOI:
[10.1016/j.rmed.2016.05.021](https://doi.org/10.1016/j.rmed.2016.05.021)

Document Version
Author Accepted version

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Behavior change theory, content and delivery of interventions to enhance adherence in chronic respiratory disease: a systematic review

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22 **Key words:** adherence, respiratory, systematic review, behaviour, theory

23 **Word count:** 2046

24 **Running title:** Behavior change theory in respiratory disease

25 **Conflicts of interest**

26 The authors declare that they have no competing interests.

27

28 **ABBREVIATIONS LIST**

29 BCT: behavior change technique

30 COPD: chronic obstructive pulmonary disease

31 CF: cystic fibrosis

32 IQR: interquartile range

33 MRC: medical research council

34 mRCT: metaregister of controlled trials

35 OSA: obstructive sleep apnea

36 Psych: psychologist

37 RT/PT: respiratory therapist/physical therapist

38 SD: standard deviation

39 SDM: shared decision making

40 SEM: standard error of the mean

41 TIDiER: template for intervention description and replication

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ABSTRACT

Background: We sought to describe the theory used to design treatment adherence interventions, the content delivered, and the mode of delivery of these interventions in chronic respiratory disease.

Methods: We included randomized controlled trials of adherence interventions (compared to another intervention or control) in adults with chronic respiratory disease (8 databases searched; inception until March 2015). Two reviewers screened and extracted data: post-intervention adherence (measured objectively); behavior change theory, content (grouped into psychological, education and self-management/supportive, telemonitoring, shared decision-making); and delivery. “Effective” studies were those with $p < 0.05$ for adherence rate between groups. We conducted a narrative synthesis and assessed risk of bias.

Results: 12,488 articles screened; 46 included studies ($n=42, 91\%$ in OSA or asthma) testing 58 interventions ($n=27, 47\%$ were effective). Nineteen (33%) interventions (15 studies) used 12 different behavior change theories. Use of theory ($n=11, 41\%$) was more common amongst effective interventions. Interventions were mainly educational, self-management or supportive interventions ($n=27, 47\%$). They were commonly delivered by a doctor ($n=20, 23\%$), in face-to-face ($n=48, 70\%$), one-to-one ($n=45, 78\%$) outpatient settings ($n=46, 79\%$) across 2-5 sessions ($n=26, 45\%$) for 1-3 months ($n=26, 45\%$). Doctors delivered a lower proportion ($n=7, 18\%$ vs $n=13, 28\%$) and pharmacists ($n=6, 15\%$ vs $n=1, 2\%$) a higher proportion of effective than ineffective interventions. Risk of bias was high in >1 domain ($n=43, 93\%$) in most studies.

Conclusions: Behavior change theory was more commonly used to design effective interventions. Few adherence interventions have been developed using theory, representing a gap between intervention design recommendations and research practice.

INTRODUCTION

Adherence, the extent to which patients' behaviors follow a recommended treatment path¹, is widely reported as being sub-optimal.² Chronic respiratory disease is no different – it is reported that between 30-50% of patients take treatment as prescribed.³⁻⁵ This lack of adherence is not inconsequential; low adherence is associated with treatment failure and poor health outcomes.⁵⁻⁷

Many researchers have attempted to change adherence to prescribed treatments in chronic respiratory disease by developing behavior change interventions.⁸⁻¹¹ Medical Research Council (MRC) guidance states that these interventions should be developed systematically and involve the use of behavior change theories.¹² Yet studies of other complex interventions demonstrate that behavior change theories are rarely used.^{12,13} The TIDieR reporting guidelines also recommend that the behavior change theory used to design the intervention should be reported alongside a detailed description of what was actually delivered (content) and how this was delivered (who provided the intervention, what was the mode of delivery, where was it delivered, in what frequency and over what duration).¹⁴

Systematic reviews of interventions to change adherence behavior in chronic respiratory disease have synthesised the evidence for the effectiveness of these interventions.^{2,15} But they have not focused specifically on synthesising data on whether behavior change theories were used in their development, nor have they explored the content or the delivery of these interventions. These data are needed to inform the development of new interventions and to allow implementation of effective interventions into clinical practice. This systematic review describes the behavior change theories used to develop adherence interventions (compared to another intervention or usual care) in adults with chronic respiratory disease, the content that was delivered, along with who provided it, its mode of delivery, where it was delivered, in what frequency and over what duration.

MATERIALS AND METHODS

Inclusion and exclusion criteria for studies

We included randomized controlled trials (RCTs) of adults ≥ 18 years old, with a clinical diagnosis of chronic respiratory disease (asthma, bronchiectasis, chronic obstructive pulmonary disease [COPD], allergic bronchopulmonary aspergillosis, interstitial lung disease, obstructive sleep apnea [OSA]¹⁶ or cystic fibrosis [CF]) who received an adherence to treatment (any treatment with the exception of exercise) intervention compared to another intervention or usual care, where adherence was objectively

measured (e.g. electronic monitoring, pill counts or medication possession data). Only objective measures of adherence were included because subjective adherence measurements (e.g. self-report questionnaire) are known to over-estimate adherence.¹⁷ Studies measuring adherence to exercise or those available in abstract form only, were excluded. No attempt was made to identify unpublished studies. This review was not registered on PROSPERO but the protocol can be obtained from the authors. No ethical approval was required for this study.

Search strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), Medline, EMBASE, CINAHL, International Pharmaceutical Abstracts, PsycINFO, Sociological abstracts and PEDro from inception until March 2015 using the search strategy outlined in the online supplement. Language was restricted to English. We searched the metaRegister of controlled trials (mRCT), ClinicalTrials.gov and the WHO trials portal using the keywords 'adherence', 'compliance' and 'concordance.'

Study selection

Pairs of reviewers screened titles, abstracts and subsequent full texts (AMcC, CR, NY, CM, BON, JB, CH plus three research assistants. All screeners received written instructions on screening from AMcC to ensure consistency in approach (available on request from AMcC). Conflicts were resolved between pairs and disagreements were resolved by a third reviewer (AMcC or CH).

Data extraction

Pairs of reviewers (AMcC and CR, NY and CM) extracted data on study design, participants and the number of interventions tested (e.g. a three-arm study where two interventions were tested against usual care would have two intervention arms). For each intervention, we extracted (from the abstract, introduction, methods, results or discussion sections) the name of any behavior change theory used, the content delivered, who provided the intervention, the mode of delivery, where it was delivered, in what frequency and over what duration (items 2-8 of the TiDieR checklist¹⁴). Reviewers also extracted mean (\pm SD, 95% CI or SEM) or median (IQR or range) and p values for objective adherence to treatment in intervention and control groups at the end of study follow-up. If no other measures were reported, mean change, mean difference (\pm SD) or the number of participants (%) categorized as adherent were extracted. Pairs of reviewers (AMcC and CR, NY and CM) assessed each study's risk of bias (as high, unclear or low, using the Cochrane Collaboration's tool for assessing risk of bias) across six domains:

random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting.

Synthesis of results and summary measures

Included studies could not be meta-analysed due to heterogeneity in the outcome measures used and the interventions tested. Without meta-analysis, we could not determine the statistical importance of theory, content and delivery using meta-regression. Consequently, we narratively described the behavior change theories used in intervention development, and provided descriptive statistics of what content was delivered, who provided the intervention, what the mode of delivery was, where it was delivered, in what frequency and over what duration. Classification of the content of complex interventions is difficult, due to overlap in content between different interventions. However, we grouped interventions by content (psychological; education and supportive or self-management; telemonitoring; and shared decision-making interventions) by consensus within the research team. More than one clinician may have delivered a single intervention; each profession is counted separately. We categorized interventions into “effective” ($p < 0.05$ for adherence rate between groups), or “ineffective” ($p > 0.05$) by whether they were associated with statistically significant improvements in objective adherence.

RESULTS

Summary of studies

Screening resulted in the inclusion of 46 studies (Figure 1) testing 58 interventions in 12,415 participants (median 100 per study, range 12-6431) (e-Table 1-3). Most studies included patients with OSA or asthma (Figure 1). Twenty-seven interventions (47%) were shown to be effective (e-Table 4-6).

Behavior change theory used in intervention development

Most ($n=39$, 67%) interventions were not based on behavior change theory (Figure 2). Nineteen interventions (33%) (from 15 studies) were designed using 12 different behavior change theories (Table 1). A higher proportion of effective interventions ($n=11$, 41%) used behavior change theory to design their intervention than ineffective interventions ($n=8$, 26%) (Figure 3).

Content

Most (n=27, 47%) interventions delivered educational, self-management or supportive content (Figure 2). Educational, self-management or supportive content was more common for ineffective interventions (n=17, 55%) than effective interventions (n=10, 37%) (Figure 3). Detailed descriptions of intervention content are provided in eTable 1-3.

Delivery

The majority of interventions were delivered by doctors or nurses, on a face-to-face, one-to-one, out-patient basis across two to five visits, at various frequencies over the course of one to three months (Figure 2). Doctors delivered a lower proportion of effective interventions (n=7, 18%) compared to ineffective (n=13, 28%). Pharmacists delivered a higher proportion of effective (n=6, 15%) compared to ineffective interventions (n=1, 2%). No other differences could be identified in who provided the intervention, the mode of delivery, where was it delivered, in what frequency and over what duration.

Risk of Bias

Three studies had a low risk of bias. We rated the remaining studies as having an unclear or high risk of bias in one or more domains (high risk in ≥ 1 domains, n=28; unclear risk in ≥ 1 domains, n=43) (Figure 4, e-Figure 1).

DISCUSSION

Most adherence interventions did not use behavior change theories in their development. Of those that did, they used 12 different behavior change theories. Use of behavior change theory was more common amongst effective interventions. Most adherence interventions used educational and self-management or supportive interventions delivered on a face-to-face, one-to-one out-patient basis (up to five visits, one to three months). Interventions with educational, self-management or supportive content constituted over half of ineffective interventions. Doctors delivered a lower proportion of the effective interventions, and pharmacists a higher proportion of effective interventions (compared to ineffective interventions).

One third of studies reported using behavior change theories in their development and more studies in the effective interventions group used behavior change theory, adding weight to the recommendations to use behavior change theory to design interventions.¹² Our findings are limited by the small number of

studies that reported using theory, and the extent to which these theories were used to inform the intervention is not known. Given the poor reporting noted in behavior change interventions, it is also possible that more studies used theory but did not report it.¹⁶ Only self-efficacy theory and social cognitive theory were used in more than one study. This is not surprising, given the range of behavior change theories that exist. At the time that many of these interventions were designed, there was no clear cut way of defining which theories to use and how to use them. Michie and colleagues have attempted to remedy this issue by creating the Theoretical Domains Framework, in which they have combined 128 explanatory constructs from 33 behavior change theories into a single framework of 14 domains.^{13,20}

Interventions using education, self-management or supportive approaches were more common amongst ineffective interventions. The categories which were used to group content were broad and the educational content varied greatly between studies, from group education²¹ to patient advocates.²² Defining intervention content and grouping similar interventions is a common challenge when reviewing behavior change interventions and is a limitation of this review. This is due to the variety of interventions used and is, in part, due to poor reporting of the exact content of interventions.²³ The Behavior Change Technique (BCT) Taxonomy (published after this review commenced) attempts to overcome this issue by defining the individual components of behavior change interventions in a reproducible way by providing definitions and examples.²⁴ It has been used in other systematic reviews to extract the components of existing interventions.²⁵ The main challenge with using this approach is that the original intervention content was not designed to be defined by behavior change techniques and is so poorly reported that it makes it nearly impossible to use this approach.²⁵ Future adherence intervention studies should describe their interventions using the BCT Taxonomy²⁴ and report them using reporting checklists such as TIDiER and CONSORT.^{14,26} Many studies in this review reported study designs and outcomes poorly; the use of these checklists would also address these issues. An adherence intervention for bronchiectasis has been developed using this approach, and is currently under further development prior to feasibility and pilot testing.²⁷

Findings from this review demonstrated that a higher proportion of effective interventions were delivered by pharmacists, and a lower proportion by doctors. It is possible that pharmacists have more time, and receive more training on how to monitor and change adherence behaviour, or that those interventions led by pharmacists contained components that specifically targeted the underlying barriers and facilitators to adherence. No other differences in delivery were identified. It is likely that

there is no 'one-size fits all' approach to intervention delivery and will depend on the healthcare context in which the intervention is likely to be effective.²⁸ As an example, in cystic fibrosis, a group-based primary care intervention delivered by a general practitioner and/or practice nurse is unlikely to be effective given that most care is delivered by specialists in secondary care and patients are treated in isolation of one another. In contrast, for COPD, this approach might be appropriate given that they already receive annual reviews and have contact with their general practitioner and practice nurse (if in the United Kingdom). Thus, researchers should involve stakeholders in intervention design to identify the most appropriate delivery method for their patient population and healthcare context.²⁹

Most studies in this review included those with OSA or asthma, making the findings more generalizable to those populations. Clear gaps exist for patients with COPD, bronchiectasis and CF, who are known to have low adherence.⁵⁻⁷ Research is beginning to focus on developing adherence interventions for these groups^{27,30,31} and this is an area for further development.

Our data show that the education, self-management and supportive approaches that may be commonly used in clinical practice may not always be effective at improving adherence, and that using theory-based interventions may be more useful for clinicians to implement with patients.

Strengths of this review include: its broad scope, incorporating all adherence interventions across any chronic respiratory disease or clinical setting, and the inclusion of studies reporting objective measures of adherence. Comparisons between the use behavior change theory, content and delivery were descriptive and based on small numbers of studies and should be interpreted with caution. The heterogeneity of included interventions made categorization of intervention content problematic. We only extracted data on adherence from final study visits, meaning any interim effects have not been captured. Our search was restricted to English language and we did not contact authors to identify unpublished studies, meaning the results presented could be affected by publication bias. We did not extract any data on recruitment rates for individual studies which may affect the generalisability of the findings presented.

Conclusion

Behavior change theory use was more common amongst effective interventions, providing evidence that this is an important consideration for future adherence interventions. Few adherence interventions

242 have been developed using theory, representing a gap between medical research guidance and research
243 practice.

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245 **Acknowledgements**

246 We would like to thank Dr Nicola Goodfellow, Dr Janine Cooper and Dr Anna Millar from the School of
247 Pharmacy, Queen's University Belfast for their assistance in screening of study abstracts.

248 **Funding**

249 This work was supported by The Bupa Foundation (Grant number TBF-MR12-015F). AMcC is funded by
250 the National Health and Medical Research Council (Australia) for work unrelated to this review (grant
251 number 1044904).

252 **Author's contributions**

253 All authors made substantial contributions to the conception or design of the work and interpretation of
254 the data. AMcC, CR, CH, JB, B'ON, NY, CM screened abstracts. AMcC, CR, NY and CM screened full text
255 and extracted data. AMcC, NY and CM analysed data. All authors contributed to the drafting and
256 revision of the manuscript for important intellectual content, and gave final of the version to be
257 published. All authors agree to be accountable for all aspects of the work in ensuring that questions
258 related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
259 AMcC had full access to all of the data in the study and takes responsibility for the integrity of the data
260 and the accuracy of the data analysis.

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FIGURE LEGENDS

Figure 1. PRISMA chart of review process

Figure 2. Summary of behavior change theory, content, and delivery of all interventions

SDM: shared decision making

RT/PT: respiratory therapist/physiotherapist

Psych: psychologist

Unknown: not reported in the manuscript

Numbers in bars denote percentage with each characteristic

Figure 3. Summary of behavior change theory, content, and delivery of effective and ineffective interventions

SDM: shared decision making

RT/PT: respiratory therapist/physiotherapist

Psych: psychologist

Unknown: not reported in the manuscript

Numbers in bars denote percentage with each characteristic

Figure 4. Summary of risk of bias of included studies

Table 1. Psychological theories used in the design of adherence interventions for OSA, asthma and COPD

Psychological theories used
Compliance therapy model ¹⁰
Decisional balance ³²
Health Belief Model ³³
Horne and Weinman's Benefit-risk model ³⁴
Patient navigator model ²²
Prospect theory ³⁵
Protection motivation theory ³⁶
Self-efficacy theory ^{32,37}
Social cognitive theory ^{35,38,19,39,40}
Transtheoretical model ³⁸
Triandis theory of behavior ⁴¹
"Theory-based" but specific theory not reported ^{42,43}